

REMARKS

Status Summary

Currently, claims 1-26 are pending. Claims 1-26 presently stand rejected. Upon entry of this amendment, claims 1, 5, 6, 21, and 23 will be amended. Claims 7-20 will be canceled without prejudice. New claims 27-36 will be added. Thus, upon entry of this amendment, claims 1-6, 21-26, and 27-36 will be pending. Reconsideration of the application and entry of the amendment is respectfully requested.

Claim Rejections under 35 U.S.C. § 102(b)

Claims 1-4, 6-16, 18-22, and 25-26 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,467,793 to Ender (hereinafter, "Ender").

Recitation of the Independent Claims Rejected under 35 U.S.C. § 102(b)

Independent claim 1 recites a longitudinally extending intrafocal plate for securing bone fractures. The intrafocal plate consists of a flat, elongated intrafocal plate element having a surface at one end thereof defining a top, bottom, a leading end, and a trailing end and sized to overlay a fracture site. The elongated intrafocal plate has a longitudinally extending intrafocal resilient body element secured with the intrafocal plate element adjacent to but spaced apart from the trailing end of the surface of the plate element so that the leading end of the surface of the plate element extends above the location at which the resilient body element is secured to the surface of the plate element. Also, the resilient body element is secured with the plate element adjacent to but spaced apart from the trailing end of the surface so as to define an overhanging

heel between the location at which the resilient body element is secured to the surface of the plate element and the trailing end of that surface. The overhanging heel extends downwardly below the location at which the resilient body element is secured to the surface of the plate element. The heel serves to help stabilize the fracture site. The resilient body element is formed to extend generally in a lengthwise direction of the surface and wherein the other end of the resilient body element defines a pin element.

Independent claim 6 recites a longitudinally extending intrafocal plate for securing metaphyseal bone fractures. The intrafocal plate consists of a flat, elongated intrafocal plate element having a surface at one end thereof with one or more apertures therein in defining a top, bottom, leading end and trailing end and sized to overlay a fracture site. At least two screws extend through the flat, elongated intrafocal plate. The intrafocal plate has a longitudinally extending intrafocal resilient body element affixed to and depending from the trailing end of the surface so that the body element forms an acute angle with the surface and extends generally in a lengthwise direction of the surface. The body element is adjacent to but spaced apart from the trailing end of the surface of the plate element so that the leading end of the surface of the plate element extends above the location at which the resilient body element is affixed to the surface of the plate element. Also, the resilient body element is affixed with the plate element adjacent to but spaced apart from the trailing end of the surface so as to define an overhanging heel between the location at which the resilient body element is affixed to the surface and the trailing end of the surface. The overhanging heel extends downwardly below the location at which the resilient body element is affixed to the surface of the plate element. The heel serves to help stabilize the fracture site. The

body element defines a shoulder at one end at the juncture of the body element and the surface with a pin at the other end of the body element.

Independent claim 21 recites an intrafocal plate for stabilizing a fracture site. The intrafocal plate includes a plate element having a first end and a second end. The intrafocal plate also includes a body element having a sinuous shape and connected between the first end and the second end of the plate element. The body element has a first portion, a second portion and a third portion, wherein the first portion curves away from the plate element, the second portion curves toward the plate element and the third portion curves away from the plate element. The second end of the plate element stabilizes the fracture site.

Applicant's Arguments Against the Rejections under 35 U.S.C. § 102(b)

Applicant respectfully submits that Ender does not anticipate independent claims 1, 6, and 21 or the claims that depend therefrom. In particular, Ender does not disclose all the features of claims 1, 6, and 21.

Claims 1 and 6 have been amended to include the transitional phrase of "consisting of." This transitional phrase excludes any element, step, or ingredient not specified in the claim. (See MPEP § 2111.03, citing In re Gray, 53 F.2d 520, 11 USPQ 255 (CCPA 1931).) Consequently, the pending claims exclude devices that include elements other than those recited in the claims.

Ender discloses a device that includes resilient bone nails **4** and an insert member **5** that is a separate modular component from the resilient bone nails **4**. The bone nails **4** are provided at their respective distal ends with a coupling member (not

shown). The insert member **5** has a guide channel **6** and a flange contacting the outer surface of the bone **1**. (See Ender, col. 4, line 41- col. 5, line 9.) In particular, Ender discloses that “the insert member **5** has a guide channel **6** (see Figures 2 to 7) which is arranged such that the nails, when forcibly introduced, run into the medullary canal **3** in the desired manner. Furthermore, the insert member **5** is provided with a flange **7** contacting the outer surface of the bone and preventing the insert member **5** from entering the medullary canal for too great a distance.” (See Ender, col. 4, line 65- col. 5, line 4.) The insert member **5** is inserted into the impact hole whereupon the bone nails **4** are forcibly introduced and rotated for reducing or repositioning the fractured area. (See Ender, col. 4, lines 56-59.)

As clearly set forth in Ender, the insert member is specifically included in the manner described above to prevent the impact hole formed in the bone for introducing the bone nails from becoming enlarged when the bone nails are introduced into the bone. The insert member is also specifically included in the manner described above to prevent the bone nails from entering the bone at too great a distance, making it difficult to remove the bone nails at a future time. The foregoing clearly demonstrates that the intrafocal plate as recited in claims 1 and 6 is not disclosed, taught, suggested by or inherent in Ender because Ender includes a tubular insert member. The insert member is not flat on the side that faces bone and from which the nails will extend, because it needs the tubular portion for insertion into the impact hole as recited in Ender.

Further, claim 6 of the present application also recites that at least two screws extend through the flat plate element. Ender does not disclose using screws that extend through the device.

Claim 21 has been amended to clarify that the sinuous shape of the body element includes a first portion, a second portion and a third portion, wherein the first portion curves away from the plate element, the second portion curves toward the plate element and the third portion curves away from the plate element. Ender discloses that the bone nails **4** are formed of an elastic material that curves in a single direction as shown in Figure 1 as the bone nails **4** are being guided through the guide channel **6** in the insert member **5** into the medullary canal of the bone. (See Ender, col. 4, lines 46-50 and Figure 1.) Ender does not disclose, teach, or suggest that the bone nails are formed as, or are capable of forming, a sinuous shape. Furthermore, Ender does not disclose, teach, or suggest a body element having a sinuous shape having first, second and third varying curved portions.

For at least the reasons set forth above, Ender does not anticipate claims 1, 6, and 21. Since claims 2-4 depend from claim 1, and claims 22 and 25-26 depend from claim 21, applicant respectfully submits that these claims are also not anticipated by Ender. Applicant, therefore, respectfully requests that the rejections of claims 1-4, 6, 22, and 25-26 under 35 U.S.C. § 102(b) be withdrawn and the claims allowed at this time.

Claim Rejections – 35 U.S.C. § 103

Claims 5 and 17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ender in view of U.S. Patent No. 4,483,335 to Tornier (hereinafter, "Tornier"). Claims 23-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over

Ender in view of U.S. Patent No. 5,013,314 to Firica et al. (hereinafter, "Firica"). These rejections are respectfully traversed.

Arguments Against the Rejections under 35 U.S.C. § 103

Neither Tornier nor Firica overcome the shortcomings of Ender. Claims 23-24 depend from claim 21 described above. Claim 5 recites an intrafocal plate for securing bone fractures. The intrafocal plate consists of a flat, elongated intrafocal plate element having a surface at one end thereof defining a top, bottom, leading end and trailing end and sized to overlay a fracture site. The intrafocal plate has a longitudinally extending intrafocal resilient body element integral to the surface adjacent to but spaced apart from the trailing end of the surface of the plate element so that the leading end of the surface of the plate element extends above the location at which the resilient body element is integral to the surface of the plate element. Also, the resilient body element is integral with the plate element adjacent to but spaced apart from the trailing end of the surface so as to define an overhanging heel between the location at which the resilient body element is integral to the surface of the plate element and the trailing end of the surface. The overhanging heel extends downwardly below the location at which the resilient body element is integral to the surface of the plate element. The heel serves to help stabilize the fracture site. The other end of the body element defines a pin with the intrafocal plate including one or more screws for insertion through one or more apertures defined in surface of the plate element.

Regarding claim 5, it is noted that the transitional phrase of "consisting of" has been added to the claim, which excludes any element, step, or ingredient not specified

in the claim. Neither Ender nor Tornier disclose, teach, or suggest an intrafocal plate consisting of all the features and elements as recited in claim 5.

As stated above, Ender does not disclose, teach or suggest the intrafocal plate having a longitudinally extending intrafocal resilient body element integral or connected to the plate element. Tornier discloses a nail **8** that is bent twice at one end in opposing directions so as to form a shoulder **8a** substantially perpendicular to the preceding portion of the nail and to form a flattened plate portion **8b** that extends outward from the shoulder **8a**. The flattened portion or plate **8b**, which remains exterior to the bone, may be fixed to the inner side of the process by means of a screw **9**, if required. Tornier does not disclose an overhanging heel that extends backward in the opposite direction of the plate **8b** from the shoulder **8a**. The plate portion **8b** only extends on one side of the shoulder **8a**. The plate **8b** does not extend on both sides of the shoulder **8a**. Thus, Tornier does not disclose, teach or suggest an intrafocal plate consisting of all the features and elements as recited in claim 5.

Further, to change Ender in the manner suggested would destroy its principles of operations. If the proposed modification changes the principle of operation of the prior art reference, then the reference is not sufficient to render the claims *prima facie* obvious. (See M.P.E.P. § 2143.01, citing In re Ratti, 270 F.2d 810 (CCPA 1959).)

Claim 5 recites in closed language that an intrafocal plate includes a flat plate element, a body element and a screw. To remove the tubular guide channel from the insert member in Ender so that the insert member would be flat would prevent the use of bone nails and, in turn, the need for the insert member as disclosed therein. Further, to make the insert member flat on the side that the nail extends through and that the

faces the bone would prevent it from being "inserted" into the impact hole as required by Ender. Thus, applicant submits that the proposed combination of Ender's device with Tornier's alternate arrangement would change the operating principle of the device and, in particular, the insert member of Ender. Therefore, one of ordinary skill in the art would not look to modify Ender in the manner suggested and the proposed combination of Ender's device with Tornier's alternate arrangement does not render claim 5 *prima facie* obvious.

Claim 21 from which claims 23-24 depend has been amended to incorporate some features of claim 23. Further, claim 23 has been amended to incorporate a fourth portion that curves toward the plate element. As stated above, Ender does not disclose, teach, or suggest an intrafocal plate consisting of all the features and elements recited in claim 21.

Applicant respectfully submits that Firica also does not disclose, teach, or suggest a body element having a first portion that curves away from the plate element, a second portion that curves toward the plate element and a third portion that curves away from the plate element as recited by claim 21. As shown in Figures 66-70, Firica discloses a plate system having a body element that only has two curves in a sinuous shape. Again, there is no disclosure in the specification of Firica of a rod that is bent more than twice relative to the end anchored to the bone such that two portions extend away from the bone and one portion extends toward the bone in sinuous shape. Even if Firica was to show three curved portions, the portions would not curve in the manner recited in claim 21. Further, Firica does not disclose, teach, or suggest a fourth portion

that curves toward the plate element as recited in claim 23. Therefore, claims 23 and 24 are not rendered obvious by the Ender and/or Firica.

For the reasons set forth above, claims 5 and 23-24 are not rendered obvious by the cited references. Accordingly, applicant respectfully submits that the rejections of claims 5 and 23-24 under 35 U.S.C. § 103(a) should be withdrawn and the claims allowed at this time.

New Claims

New claims 27-36 have been added by this amendment as indicated above. Claims 27 and 32 are independent claims and recite a method of treating or securing metaphyseal bone fractures using an intrafocal plate. The methods include providing an intrafocal plate having a plate element with a trailing end defining an overhanging heel. The intrafocal plate is pushed into the bone such that the heel overlays the fracture site to stabilize the fracture site and to prevent over reduction.

Support can be found, for example, in the specification beginning on page 14 of the originally filed application. The specification recites that "a modification of the intrafocal plate apparatus described above is shown in FIGS. 7A, 7B; 8A, 8B; and 9A, 9B, which provides for a heel or overhang at the tail of the plate element in order to prevent the intrafocal plate from producing 'over reduction' and thereby forcing the bone fragment beneath the plate too far to the other side of the bone when the intrafocal plate has been fully inserted through the fracture into the bone. Further, the heel or overhang at the trailing end of the plate can further serve to stabilize the fracture against the inner cortex of the bone." (See application, page 14, lines 4-11. Support can also be found in

the originally filed applications at least on page 14, line 12- page 15, line 2, and on page 16, lines 10-21.

Ender, Tornier and Firica, singularly or in combination, do not disclose, teach or suggest overlaying a fracture site with an overhanging heel of a plate element. To the contrary, Ender, Tornier and Firica teach methods of reducing or repositioning and fixing a fracture site that are performed in the exact opposite manner of the methods recited in claims 27 and 32. In each of the cited references, the bone nails are inserted into the bone at an end opposite the fracture site. The ends of the bone nails that enter the bone are directed through the medullary canal to the fracture site. The bone nails are then secured to the bone with a flange bearing against the bone at a location remote from the fracture site. Thus, Ender, Tornier and Firica teach away from claims 27 and 32.

Therefore, claims 27 and 32 should be allowed. Claims 28-31 depend from claim 27 and claims 33-36 depend from claim 32. Therefore, these claims should also be allowed.

CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the claims of the present application are now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

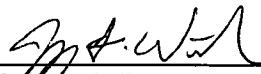
If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,
JENKINS, WILSON, TAYLOR, & HUNT, P.A.

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